EXHIBIT C

FDA NEWS RELEASE

FDA provides update on its ongoing investigation into valsartan products; and reports on the finding of an additional impurity identified in one firm's already recalled products

For Immediate Release:

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The U.S. Food and Drug Administration is updating the public on the agency's ongoing investigation surrounding the recent voluntary recall of several drug products containing the active pharmaceutical ingredient (API) valsartan, used to treat high blood pressure and heart failure.

The FDA's latest testing of products shows an additional unexpected impurity in three lots of Torrent Pharmaceuticals' recalled valsartan drug products (/safety/recalls-market-withdrawals-safety-alerts/updatedadditional-lots-added-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall). This second impurity, N-Nitrosodiethylamine (NDEA) is a known animal and suspected human carcinogen. These Torrent products were included in the company's recall on August 23, 2018.

The FDA and the European Medicines Agency have learned that Zhejiang Huahai Pharmaceuticals (ZHP) found NDEA in several batches of its valsartan API. The FDA immediately began retesting all valsartan API and products, including both recalled products and those currently marketed in the United States, for NDEA. Based on FDA testing to date, the agency discovered NDEA in some of ZHP's valsartan API. This impurity was also found in Torrent's valsartan 160mg (lot BV47D001) and 320mg (lots BV48D001 and BV48D002) tablets, which were made using API from ZHP and were part of the earlier recall. The FDA's testing shows that not all products made using ZHP valsartan API contain the NDEA impurity.

"As we continue to investigate the root cause of the impurities found in products that contain valsartan, our scientists are testing these products to better understand these impurities and to ensure they're not present in other products. We're also taking steps to make sure we're providing stringent oversight of manufacturing processes to reduce the likelihood that impurities could be introduced into other products," said FDA Commissioner Scott Gottlieb, M.D. "As we expand our investigational efforts, we'll continue to make sure the public has the most up-to-date information. We'll also continue to work with global regulatory agencies to learn as much as we can about how these impurities came about and how they may affect patients' health around the globe."

The FDA is continuing to test all products that contain valsartan for NDEA and related impurities. If the agency finds NDEA in products that have not been recalled, the FDA will work with companies to ensure all affected products are removed from the market. The agency is also evaluating the risks NDEA in these products poses to patients. The FDA expects to complete this risk analysis in the coming days and will continue to provide updates to the public as new information becomes available.

Like N-Nitrosodimethylamine (NDMA), which was found in the recalled valsartan products, NDEA is also formed from a specific sequence of manufacturing steps and chemical reactions. In addition to the FDA's testing, the agency will post a preliminary method for detecting NDEA. Manufacturers and global regulators can use this method to screen other products for the potential presence of this impurity.

Additionally, the agency will update the list of products included in the recall (/media/115390/download) and the list of products not included in the recall as products are tested for NDEA and as more information becomes available. If you are taking a valsartan product, be sure to check the lists, as they may change.

The FDA reminds patients taking valsartan from a recalled lot to continue taking their current medicine until their doctor or pharmacist provides a replacement or a different treatment option. Any patient taking valsartan from a recalled lot who has not yet spoken to their pharmacist or doctor should do so promptly. At this time, the FDA's testing supports the conclusion that not all valsartan products contain NDMA or NDEA, so pharmacists may be able to provide a valsartan medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Related Information

- FDA updates on valsartan recalls (/drugs/drug-safety-and-availability/fda-updates-valsartan-recalls)
- EMA update on review of valsartan medicines (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/09/news_detail_003015.jsp&mid=WC0b01ac058004d5c1) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Health Canada advises of a second impurity linked to recalled valsartan drugs (http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67746a-eng.php) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

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